



## EU Certificate Changeover Q&A



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### I. INTRODUCTION

On January 15 2009, the Food and Drug Administration (FDA) published in the Federal Register notice that the FDA will be relinquishing responsibilities for certification of fishery product exports to the European Union from the United States (**Docket No. FDA-2004-D-0043, CFSAN 200843**).

This guidance document provides a list of questions that frequently have been asked about the changes to fishery products export certification, and the answers to those questions. This document is being issued to help the food industry and others comply with the new guidance established by the Federal Register Notice.

### II. EU CERTIFICATION FOR EXPORTS QUESTIONS AND ANSWERS BACKGROUND

#### **What is changing?**

The FDA intends to proceed with a Certification Referral Program to the National Oceanic and Atmospheric Administration Seafood Inspection Program (NOAA SIP) to include all fish and fishery products for export to EU or European Free Trade Association (EFTA) member countries.

#### **Why is there a change from the FDA?**

The FDA has experienced significant increases in food safety responsibilities and declines in resources available for food safety. In order to carry out public health activities and regulatory oversight that are intended to protect the U.S. consuming public, FDA has found it necessary to focus these resources to higher priority programs (based on public health significance) and has determined that it can no longer justify the use of its limited food safety resources for issuance of EU Export Certificates, especially when another agency has resources available to issue these certificates and has as part of their mission the issuance of such certificates.

#### **When does this go into effect?**

The effective date for the transition is February 17, 2009.

#### **How do I comment on the proposed changes?**

Interested persons may submit to the Division of Dockets Management electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at

<http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.regulations.gov>.

**Where can I get more information?**

Additional information on the FDA's website at <http://www.fda.gov/>. The guidance will be available on the FDA website <http://www.cfsan.fda.gov/guidance.html> and <http://www.cfsan.fda.gov/~dms/eucert.html>. Additional information can be found at the USDC Seafood Inspection Program website, <http://www.seafood.nmfs.noaa.gov/>. The Federal Register can be accessed at <http://www.accessdata.fda.gov/scripts/oc/ohrms/dailylist.cfm?yr=2009&mn=1&dy=15>

**III. REQUIREMENTS FOR FISHERY PRODUCT EXPORT TO THE EUROPEAN UNION**

**How is a request for an EU certificate submitted to NOAA?**

The request for EU Export form and required payment information is located at the NOAA website. Follow instructions regarding filling out the request, payment and certificate completion. <http://www.seafood.nmfs.noaa.gov/>. If computer access is limited, regional inspection offices can be called directly for information regarding requests. The office contacts are listed in section VII of this document.

**Do I have to submit a request to both FDA and NOAA?**

No. The FDA will be referring all requests for export certification to the NOAA SIP. Establishments wishing to export fish and fishery products to the EU and EFTA will still need to apply to FDA for inclusion on the US FDA -EU Export Certification Lists.

**Are there other agencies certifying exports to the EU?**

After the 30 day transition period, on Feb. 17, 2009, NOAA SIP will be the only EU recognized competent authority issuing fishery product export certification.

**Who may submit requests for fishery product export to NOAA SIP?**

Anyone may request certificates for fishery product export to the EU. The European Union requires that all shippers, processors and packers of fishery products entering into the EU be on the US-FDA and EU Export Certification Lists. Once an exporter and their processors are on these lists, the NOAA SIP can begin processing export certificate requests.

**Where can I access the NOAA SIP Request for Inspection form?**

This form can be found at the USDC Seafood Inspection Program website, <http://www.seafood.nmfs.noaa.gov/>. Click tab for EU Exports and follow directions for completing the request, payments and submitting requirements.

**IV. PROGRAM COSTS AND PAYMENTS**

**How much will it cost to get EU export certificates?**

Current USDC NOAA SIP approved establishments with in-plant inspectors and other contracted services such as lot inspection, will have no additional charges. Costs will be absorbed in the daily contract services. All services provided above and beyond contract hours will be billed additional time at hourly rates. USDC NOAA SIP approved establishments with HACCP QMP and IQA contracts will be charged at the flat rate of \$60 per certificate.

Requestors without a current USDC NOAA SIP approved establishment contract will be billed at the flat rate of \$90 per certificate.

**Why is there a charge for these certificates?**

The USDC NOAA SIP is a fee for service program that is required to recuperate all costs associated with the program and its services.

**Will there be an additional charge for random product inspections?**

There will be no additional costs associated with the requests that are tagged for random sampling. These inspection costs will be covered by the SIP with the payments received through the total EU certificate program.

**Is it required to prepay or can there be billing set-up?**

All non contract services will require pre-payment through the website: [Pay.gov](https://www.pay.gov).

The site will confirm payments with codes and will be included on the request for inspection prior to distribution of the certificates.

**V. PRODUCT INSPECTION**

**Will product be physically inspected prior to shipment?**

The NOAA SIP will be implementing a random sampling program for EU Export Certificate inspections. Based on product evaluation each request will fall into risk assessment categories, and then will be randomly chosen for physical product inspection. Product produced in a NOAA Approved and HACCP/QMP facilities will be inspected during quarterly audits. All products from non contracted facilities must be available if chosen for physical inspection. No additional costs will be incurred by the exporter when products are chosen for random physical sampling.

**How will the certificates be prepared?**

The NOAA SIP will be developing an EU Certificate system that will streamline all requests for EU export certification. The program will be accessed via the NOAA website at <http://www.seafood.nmfs.noaa.gov/> under the EU Exports tab.

**Will it be possible to receive pre-issued signed certificates?**

No. All NOAA SIP certificates issued will be filled out and signed/stamped per individual request.

**Is EU certification available in languages other than English?**

Yes. The USDC Seafood Inspection Program offers certification on bilingual certificates for each EU Member State.

**How long will it take to create certificates after the request is filed?**

EU Regulations require product to have certification prior to departure from exporting countries. The NOAA SIP has a long history of issuing export certificates and will provide export certification in a timely manner that will not inhibit commerce.

Export requests should be submitted with reasonable lead time that considers product inspection, loading and the creation and distribution of paperwork.

**How can the certificates be distributed?**

The request for inspection form will have a section that allows the requestor to determine the distribution of the completed certificates. Options will include FedEx Overnight or customer pickup.

## **VI. GENERAL INFORMATION**

### **What products are affected by the referral program?**

All fish and fishery products (including molluscan shellfish) are included in the referral program.

### **What is fishery product and what needs certification for EU export?**

All “Aquatic Animal Product” derived from species of the animal kingdom living in or in direct association with water, to include but not be limited to reptiles, finfish, crustaceans, mollusks and amphibians. The definition of ‘aquatic animal products’ may also include live aquatic animals destined for use as human food, stocking, relay, aquaculture, or reproduction. All require certification for import into the EU.

### **Is export certification required for fishery products intended for animal feed or pet food?**

Yes. All products derived from Aquatic Animals intended for use as animal feed, pet food and bait will require certification.

### **What happens to food that is exported without adequate certification?**

Fishery product shipments will be held or refused admission for lack of certification at the EU Border Inspection Posts. All product certification must be issued prior to the products US departure.

### **Is export certification required for food transiting the EU for exportation to another country?**

Yes. The product will require a bilingual certificate for the country of the BIP at point of entry for a product in transit. Product may also require health certificates for countries of destination other than EU Member States.

### **Are there exceptions or exemptions from export certification for any of the following?**

No. Food items of small value or quantity; Food samples for research and development or for testing purposes; Food samples for test marketing or trade samples; Food intended for charity. All fishery products entering into the EU will require export documentation for entry and transit within the EU.

## **VII. ELECTRONIC CERTIFICATION**

At this time there is no system for electronic certification. A pilot program is currently in development and may be available for use this fiscal year. Updates to possible certification programs will be listed at: <http://www.seafood.nmfs.noaa.gov/>

## **VIII. WHERE TO GET ADDITIONAL INFORMATION**

Information regarding the NOAA SIP: <http://www.seafood.nmfs.noaa.gov/>

The Federal Register can be accessed at:

<http://www.accessdata.fda.gov/scripts/oc/ohrms/dailylist.cfm?yr=2009&mn=1&dy=15>

The guidance will be available on the FDA website at: <http://www.cfsan.fda.gov/guidance.html>.

## **IX. NOAA SIP OFFICES AND CONTACT INFORMATION**

### **HEADQUARTERS**

NOAA Seafood Inspection Program  
1315 East-West Highway  
Silver Spring, MD 20910  
Telephone: 301-713-2355 Fax: 301-713-1081

### **NORTHEAST INSPECTION BRANCH**

NOAA Seafood Inspection Program  
55 Great Republic Drive  
Gloucester, MA 10930  
Telephone: 978-281-9228 Fax: 978-281-9134

### **SOUTHEAST INSPECTION BRANCH**

NOAA Seafood Inspection Program  
9887 4<sup>th</sup> Street North, Suite 220  
St. Petersburg, FL 33702  
Telephone: 727-570-5383 Fax: 727-570-5387

### **WESTERN INSPECTION BRANCH**

NOAA Seafood Inspection Program  
7600 Sand Point Way, N.E.  
Bldg 32, Room 286A  
Seattle, WA 98115  
Telephone: 206-526-4259 Fax: 206-526-4265